CORRECTIVE & PREVENTIVE ACTION PROCESS TRAINING
UTILIZING THE EPDS APPLICATION TOOL

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02/19/2010
-- PLEASE SIGN IN --

**Today’s Agenda:**

- Opening Remarks: Micki
- Pre-Test: Micki
- Training expectations: Micki/Peter
- Presentation: Micki
- Break
- EPDS hands on exercise: Peter
- Review of training expectations: Micki/Peter
- Post-Test: Micki
- Training Survey: Participants

**Corrective & Preventive Action Training**
AGENDA

- Purpose of a CAR/PAR Program
- Key Definitions and Terminology
- Root Cause Analysis
  - Basic Steps of a CAR/PAR Process
  - Basic Problem Solving Methods
- Distinction between an NCR & CAR/PAR
- QMS Source Document
- CAR/PAR Process in EPDS
- Summary
- Questions & Answers
“Quality Starts with you”

- Your participation in this training means -

You were selected because of your potential involvement in this process that will require you to execute some portion of the EPDS work flow

OR

You may have indirect involvement or be asked to contribute to the process that requires your to have a basic understanding of the CAR/PAR process

This process requires everyone’s cooperation to be successful

- THANK YOU -
Purpose of a CAR/PAR Program

• Provides a formal step by step process for completing and documenting corrective or preventive actions and form the basis for effective continual improvement efforts

• Provides a formal system to correct existing and future problems

• Provides a structured approach to help determine the root cause of nonconformance’s, system failures, or process problems

• Provides a method to document why something went (or may go) wrong and what will been done to make sure it does not happen again
Key Definitions and Terminology

- **Corrective Action Request (CAR)** - used to identify the actions needed to eliminate reoccurrence of root cause(s) of a nonconformance in procedures, processes or PMO managed activities.

- **Preventive Action Request (PAR)** - used to identify the actions needed to eliminate the cause(s) of a potential nonconformance or other potential undesirable situation in procedures, processes or PMO managed activities before they occur.
Key Definitions and Terminology

- **Corrective Action** – action to eliminate the cause of a detected nonconformance or other undesirable situation
- **Preventive Action** - action to eliminate the potential cause of a detected nonconformance or other undesirable potential situation
- **Root Cause** – identified origin of a problem
- **Objective Evidence** – data supporting the existence or authenticity of supplied information or material
WHY USE EPDS for CAR/PAR

- Requirement of the Authority
- Allows tracking of the progress
- Provides a historical record of the CAR or PAR
- Provides a “one source” location for all information regarding the problem, its root cause and corrective/preventive actions taken
- Allows metrics to be generated to show process performance
Root Cause Analysis (RCA)

- Seeks to identify the origin of a problem
  - In some cases there may be more than one
- Assumes that systems and events are interrelated
- An action in one area may trigger an action in another area (either intended or not)
- By tracing back, you can discover where the problem started and how it grew into the symptom you now face
- By knowing the **true root cause**, effective action plans can be developed to eliminate future recurrences
- By not knowing or understanding the true root cause, time and efforts are wasted and the problem will persist
Basic CAR/PAR Steps

- **Identify** the problem, nonconformance, or incident.
- **Evaluate** the magnitude of the problem and impact on the Authority.
- **Investigation** to determine root cause
- **Analysis** of the problem providing an appropriate level of documentation.
- **Action Plan** creation listing all the tasks that must be completed to correct and/or prevent the problem (inclusive of the due date)
- **Implement** the plan (by the due date).
- **Follow up** to determine effectiveness of the actions taken to prevent the problem for recurring.
Basic Problem Solving Method

- Asking “Why” five times

- The “Five Why’s” is a method for rapidly determining the root cause of a problem
- The method is to approach any problem and keep asking “Why” until an answer is found that shows the real source or origin of the problem.
- Over time it was determined that the “root cause” could be determined by asking “why” five times.
- The Five Why’s should be used by individuals and teams when trying to quickly assess and determine the source of problems.
- Most problems can be handled this way, however more complex critical problems typically require a more formal root-cause methodology including documenting the analysis.
Tips for Problem Solving

- When defining the problem, a team approach can be very effective.
- Ensure there is adequate data and objective evidence that supports the problem statement (is there really a problem).
- Brainstorm to identify all possible root causes of the problem.
- Identify which causes, if removed or changed, will eliminate the problem.
- Identify solutions that will prevent future recurrence and are within your control, meet your goals and objectives and do not cause other problems.
- Implement the most effective recommended solution (action plan).
- Observe the implementation of the recommended solutions to ensure effectiveness over time.
- Communicate successes so others may learn (lessons learned).
Issuance and Responsibility for CAR/PAR

• Issuance of CAR/PAR will go to firms with contractual responsibilities to the NTTA
• Personnel identified as the “Responsible Party” will be required to complete the EPDS workflow actions
  – The “Responsible Party”, if not directly accountable, shall work with the responsible firm to generate acceptable root cause and corrective action responses
  – The “Responsible Party” will not forward CAR/PAR to subs
  – If the “Responsible Party” has been misidentified within the process, they shall contact the Quality Teams within EPDS for resolution
PROCESS RESPONSE TIMES

To ensure timely resolution, the following response times have been established:

• The Quality Team has 5 business days to review and respond to the submitted CAR/PAR request
• The Responsible Party has 10 business days to respond with a root cause and corrective action plan (documented extensions permissible)
• The Quality Team has 5 business days to review and respond to the submitted root cause and corrective action plan
• The implementation date shall be mutually agreed upon by the Responsible Party and the Quality Team and will depend on the scope and complexity of the corrective action plan

NOTE: Business days are defined as Monday through Friday
# Distinction Between an NCR and a CAR/PAR

**NCR:**
- Identification and tracking tool used –
  - to “correct” an isolated problem when identified
  - when a resolution is needed by the Authority (and documented)
  - when the problem cannot be fixed and completed within 24 hours
  - primarily to document and correct problems found during the construction phase of a project

**CAR/PAR:**
- Problem solving process used -
  - when a root cause investigation is needed to prevent recurrence of a problem
  - when repetitive occurrences of a problem continue to occur
  - to correct problems identified with process or procedural issues
  - to correct problems identified as a result of an audit
QMS Source Document

- QM -10 is the governing document and final authority in regards to Corrective and Preventive Action process implementation
- The document can be found on the web at:
Also Available via EPDS

- Documentation specific to the currently open process is available through the EPDS help button.

Click here
1. Originator initiates and documents a request
2. Quality Team reviews and determines if valid & complete
3. Quality Team assigns a Responsible Party
4. Responsible Party determines root causes and develops action plans
5. Quality Teams reviews root cause response and determines if action plans are adequate
6. Responsible Party implements approved action plans
7. Quality Team verifies implementation of action plans
8. Quality Team validates and closes Corrective/Preventive Action Request
1. Originator initiates and documents a request

Sources:
- Observed Process / Procedural -
- Internal / External Audit Findings -
- Trends -
- Customer Complaints or Feedback -

Originators shall:
- **Clearly describe** the problem / issue
- **Make reference to** failed sections of stated requirements
- **Attach relevant documents and objective evidence**
- **Advise as to** who the “responsible party” may be
2. Quality Team reviews and determines if valid & complete

When the Quality team finds that a CAR / PAR request is not valid they may:
- Close the request and notify the Originator
- Request clarification from the Originator

When the Quality Team finds that a CAR / PAR request is valid:
- Determine if the CAR/ PAR request will be assigned to an external oversight person (EOP) who will act and manage the process on behalf of the Quality Team in steps 4 & 6

3. Quality Team assigns a Responsible Party

- Notify the Responsible Party that a CAR / PAR has been assigned to them.
EPDS PROLIANCE EMAIL NOTIFICATION

- Direct link to EPDS
- Your Action

Recommended Action: Read and Review

**EPDS Sample Email**

**From:** Proliance Notification [EPDS@ntua.org]  
**To:** Troy Federovich  
**Cc:** Ellis, Peter Claypool, Peter  
**Subject:** NCR: OMS Audit TLF10269-02 F01 (CAR0003)  
**Workspace:** PROJECT: President George Bush Tumpike - Corridor Wide (44)  
**Date Sent:** 10/13/2009 11:46 AM  
**Action by:** Troy Federovich (Assign)  
**Action_taken:** Transitioned from - Draft  
**Current state:** Active  
**Priority:** Normal  
**Expected Action:** Read and Review  
**Due Date:** 10/27/2009  
**Message:**  
Tom, Per the RFI / Submittal audit from Oct 12, 2009 the attached Corrective Action has been assigned to you and you need to review and forward it within the EPDS system by COB Oct 27, 2009. If you have any questions please let me know. Best regards, Troy

**People receiving this notice:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Department</th>
<th>Expected Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miki Ellis</td>
<td>HNTB Corporation</td>
<td>None</td>
</tr>
<tr>
<td>Peter Claypool</td>
<td>INTID Corporation</td>
<td>None</td>
</tr>
<tr>
<td>Thomas Hunt</td>
<td>McDaniel Associates, Inc.</td>
<td>Read and Review</td>
</tr>
</tbody>
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4. Responsible Party determines root causes and develops action plans

Upon receipt of a CAR / PAR the Responsible Party shall:

- **Determine the root cause** of the nonconformance to achieve the aim of preventing recurrence.
- **Establish the actions needed** that will correct the nonconformance and prevent future recurrence
- **Submit the action plan** back to the Quality Team / EOP with the date upon which the corrective action will be implemented

NOTE: The “Responsible Party” does not forward CAR/PAR to subs
5. Quality Team / EOP reviews root cause response and determines if action plans are adequate

Upon receipt of the CAR / PAR response, the Quality Team / EOP shall evaluate the root cause and corrective action plan provided. The Quality Team / EOP shall:

- If approved, forward the approved CAR / PAR to the Responsible Party for implementation.
- Reject the CAR / PAR back to the Responsible Party when the evaluation determines:
  - The root cause or causes has not been correctly identified
  - The action plan is not sufficient to prevent recurrence
  - Implementation dates are excessive
6. Responsible Party implements approved action plans
   • Upon receipt of an approved CAR / PAR (or resubmission) the Responsible Party shall implement the approved action plan by the submitted implementation date.
   • Any problems or issues that could cause a delay in the implementation of the CAR / PAR shall be reported to the Quality Team / EOP as soon as they are identified to request an extension.
   • Once the action plans in the CAR / PAR are completed the Responsible Party shall contact the Quality Team / EOP to schedule review and verification activities.
7. Quality Team / EOP verifies implementation of action plans

- Confirm the action plan has been completed by the indicated date.
- Verify the actions identified in the plan have been implemented.
- Recommend CAR / PAR for closure.
- Determine and schedule follow up when additional time is needed to generate objective evidence.
- Reject the CAR / PAR to the Responsible Party when the approved action plan has not been implemented correctly
  - The Responsible Party shall be given 5 working days to correct the issues.
  - When the action plan has not achieved the intended results of eliminating the identified root cause it shall be rejected to the Responsible Party to determine a new action plan.
8. Quality Team validates and closes Corrective/Preventive Action Request

- Validate that the actions implemented have achieved the intended results of eliminating the identified root cause
- Schedule follow-up, when advised by the Quality Manager, to determine long term effectiveness of the action taken
- Close the CAR / PAR and notify the Responsible Party
- Reject the CAR / PAR to the Responsible Party for revision (go to step 4) when the action plan has not achieved the intended results of eliminating the identified root cause
- Notify the EOP when assigned for oversight.
CAR/PAR
EPDS PROCESS STEPS

1. Originator initiates and documents a request
2. Quality Team reviews and determines if valid & complete
3. Quality Team assigns a Responsible Party
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8. Quality Team validates and closes Corrective/Preventive Action Request
SUMMARY

• Definition of a Corrective & Preventive Action
• QMS document QM-10, provides a detailed and fully documented procedure that describes the who, what, when and how to respond to a CAR/PAR Request (available on the NTTA web site and from within the EPDS application)
• Basic understanding of the steps needed for problem solving and determination of root cause or causes
• Determination and importance of implementing a Corrective Action that is effective at preventing recurrence of the problem
• Creation and basic workflow of a CAR/PAR in EPDS and response time expectations
QUESTIONS

• Additional PROCESS questions may be addressed to:
  
  Process Questions ➔ Peter Claypool at: pclaypool@ntta.org (214-224-3019)
  Process Questions ➔ Troy Federspiel at: tfederspiel@ntta.org (214-224-2468)

• Additional EPDS TECHNICAL questions may be addressed to:
  
  Technical Questions ➔ EPDS Help desk at: epdshelp@ntta.org (214-224-2405)
The mission of the North Texas Tollway Authority is to enhance mobility through responsible and innovative tolling solutions.